SODIUM CHLORIDE- sodium chloride injection
Henry Schein, Inc.

45764D/Revised: January 2008

SODIUM CHLORIDE INJECTION, USP 0.9%

DESCRIPTION:

Sodium Chloride Injection, USP, 0.9% is a sterile, nonpyrogenic solution. The osmolarity is 300 mOsmol per liter (calculated).

Each mL contains: Sodium chloride 9 mg; Water for Injection q.s. It contains no bacteriostat, antimicrobial agent or added buffer and is supplied only in single dose containers. Hydrochloric acid and/or sodium hydroxide may have been added for pH adjustment (pH 4.5-7.0).

Sodium chloride occurs as colorless cubic crystals or white crystalline powder and has a saline taste. Sodium chloride is freely soluble in water. It is soluble in glycerin and slightly soluble in alcohol.

The empirical formula for sodium chloride is NaCl and the molecular weight is 58.44.

CLINICAL PHARMACOLOGY:

Sodium chloride in water dissociates to provide sodium (Na +) and chloride (Cl —) ions. These ions are normal constituents of the body fluids (principally extracellular) and are essential for maintaining electrolyte balance.

The distribution and excretion of sodium (Na +) and chloride (Cl —) are largely under the control of the kidney which maintains a balance between intake and output.

The small volume of fluid and amount of sodium chloride provided by Sodium Chloride Injection, USP, 0.9%, when used only as a vehicle for parenteral injection of drugs, is unlikely to exert a significant effect on fluid and electrolyte balance except possibly in very small infants.

Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1 to 1.5 liters each for insensible water loss by perspiration and urine production).

Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments and sodium (Na +) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE:

Sodium Chloride Injection, USP, 0.9% preparations are indicated for diluting or dissolving drugs for intramuscular, intravenous or subcutaneous injection according to instructions of the manufacturer of the drug to be administered.

Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing of intravenous catheters.

WARNINGS:

For use in newborns, when a sodium chloride solution is required for preparation or diluting medications or in flushing intravenous catheters, only preservative free Sodium Chloride Injection, USP, 0.9% should be used.

PRECAUTIONS:

General

Consult the manufacturer's instructions for choice of vehicle, appropriate dilution or volume for dissolving the drugs to be injected, including the route and rate of injection. Inspect reconstituted (diluted or dissolved) drugs for clarity (if soluble) and freedom from unexpected precipitation or discoloration prior to administration.

Pregnancy

Pregnancy Category C—Animal reproduction studies have not been conducted with Sodium Chloride Injection, USP, 0.9%. It is also not known whether Sodium Chloride Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Chloride Injection, USP, 0.9% should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS:

Reactions which may occur because of this solution, added drugs or the technique of reconstitution or administration include febrile response, local tenderness, abscess, tissue necrosis or infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection and extravasation.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate countermeasures and, if possible, retrieve and save the remainder of the unused vehicle for examination.

OVERDOSAGE:

When used as a diluent, solvent or intravascular flushing solution, this parenteral preparation is unlikely to pose a threat of sodium chloride or fluid overload except possibly in very small infants. In the event these should occur, reevaluate the patient and institute appropriate corrective measures. (See **PRECAUTIONS** and **ADVERSE REACTIONS**).

DOSAGE AND ADMINISTRATION:

Before Sodium Chloride Injection, USP, 0.9% is used as a vehicle for the administration of a drug, specific references should be checked for any possible incompatibility with

sodium chloride.

The volume of the preparation to be used for diluting or dissolving any drug for injection is dependent on the vehicle concentration, dose and route of administration as recommended by the manufacturer.

Sodium Chloride Injection, USP, 0.9% is also indicated for use in flushing intravenous catheters. Prior to and after administration of the medication, the intravenous catheter should be flushed in its entirety with Sodium Chloride Injection, USP, 0.9%. Use in accord with any warnings or precautions appropriate to the medication being administered.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED:

Sodium Chloride Injection, USP, 0.9%, preservative free, is available as follows:

Product Code	Unit of Sale	Strength	Each
918602	63323-186-02 Trays of 25	0.9% (18 mg per 2 mL) (9 mg per mL)	NDC 63323-186-04 2 mL fill, in a 3 mL Single-Dose vial
918610	63323-186-10 Trays of 25	0.9% (90 mg per 10 mL) (9 mg per mL)	NDC 63323-186-01 10 mL Single-Dose vial
918620	63323-186-20 Trays of 25	0.9% (180 mg per 20 mL) (9 mg per mL)	NDC 63323-186-03 20 mL Single-Dose vial

Preservative Free. Discard unused portion.

Use only if solution is clear and seal intact.

Store at 20º to 25ºC (68º to 77ºF) [see USP Controlled Room Temperature].

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45764E

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Sample Package Label

SODIUM CHLORIDE

sodium chloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0404-9955(NDC:63323-186)
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SODIUM CHLORIDE (UNII: 451W47IQ8X) (CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	9 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0404-9955-10	1 in 1 BAG	01/12/2022	
1		10 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA088912	01/12/2022	

Labeler - Henry Schein, Inc. (012430880)

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